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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,185	01/09/2001	Marina Ziche	ZICHE1	5690

7590

10/01/2002

BROWDY AND NEIMARK, P.L.L.C.
624 Ninth Street, N.W.
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EXAMINER

MITRA, RITA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.	Applicant(s)	
09/756,185	ZICHE ET AL.	
Examiner	Art Unit	
Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Priority

Applicants' claim for foreign priority under 35 U.S.C. 119 (a-d) is acknowledged. This application is a continuation of PCT/EP99/04605 filed July 2, 1999, which claims priority benefit of EP 98112775.6, filed July 9, 1998. However, the specification fails to provide the certified copy of EP 98112775.6. Therefore priority date July 2, 1999 is being considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 provides for the use of a Component B where the claim recites, use of a Component B in combination with a human growth factor for the preparation of a composition for promoting angiogenesis, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 1 is a nonstatutory claim - a 'use' is not a statutory class of invention.

Claim 2 provides for the use of a Component B where the claim recites, use according to claim 1 in the treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claim 2 is a nonstatutory claim - a 'use' is not a statutory class of invention.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claims 1 and 2 are rejected as being indefinite because they lack essential steps as claimed in the process of treating wounds etc. The omitted steps are: steps whereby the desired outcome and the time for the effective treatment using Component B in combination with human growth factor can be determined.

Claim 2 is indefinite because there is no antecedent basis in claim 1 for the method of use. Claim 1 is to making the composition.

Claim 3 is rejected as being indefinite because it is not clear which "pharmaceutical composition" is intended for using as cicatrizant. Use of "A pharmaceutical composition..." is suggested.

Claims 4 is rejected as being indefinite because of the use of the phrase "two active principle are both present." Deletion of "both" may overcome this rejection.

Claim 5 is indefinite because it is not possible for the separate administration dose because component B and human growth factor are in the same composition.

Claims 4-6 are rejected as being indefinite because it is not clear which "pharmaceutical composition" of the dependent claim is intended for using as cicatrizant. Use of "The pharmaceutical composition..." is suggested.

Claim 7 is rejected as being indefinite because it is not clear which "method" is intended for the treatment of wounds, ulcers etc. Use of "A method..." is suggested. Claim 7 is also rejected as being indefinite because it lacks essential steps as claimed in the process of treating wounds, ulcers etc. The omitted steps are: steps whereby the desired outcome and the time for the effective treatment using Component B and human growth factor can be determined.

Claims 8-9 are rejected as being indefinite because it is not clear which "method" of the dependent claim is intended for the treatment of wounds, ulcers etc. Use of "The method..." is suggested.

Claim Rejections - Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,998,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 is directed to the broadest scope of the method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body. Claims 7-9 encompass the administering an effective amount of Component B set forth in claim 1 of patent US '364.

Claim 7-9 disclose a method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, comprising administering in a single administrative dose an effective amount of component B and an effective amount of a human growth factor.

This is an obvious variation of claim 1 in the patent '364, which discloses a method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, comprising administering an effective amount of component B, together with a pharmaceutically acceptable carrier.

Thus, claims 7-9 in present application and claim 1 in the patent '364 are obvious variations of a method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, comprising administering in a single administrative dose an effective amount of component B and an effective amount of a human growth factor.

Conclusion

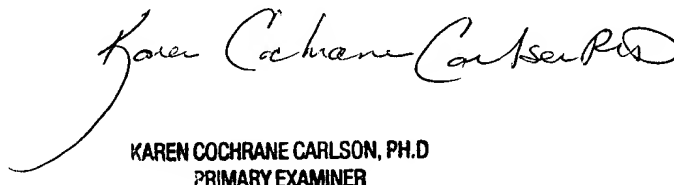
No claim is allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.
September 25, 2002



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER